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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,306	06/05/2002	Antonino Cattaneo	6596	9842

7590 12/16/2004

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,306	CATTANEO ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-19, drawn to a non-human animal transgenic for an antibody or fragments thereof and having a phenotype reminiscent of a human pathology.

Group 2, claim(s) 20, drawn to a method for diagnosis of neurodegenerative diseases by assaying tau hyperphosphorylation and/or amyloid deposition in the back or lower limb skeletal muscle sample of a patient.

Group 3, claim(s) 21, drawn to cells derivable from a non-human transgenic animal transgenic for an antibody or fragments thereof and having a phenotype reminiscent of a human pathology, that secrete the antibody.

Group 4, claim(s) 22, drawn to a method of using cells for selecting molecules pharmacologically effective in neurodegenerative and or muscular pathologies, and or immune disorders, wherein the cells are derivable from a non-human transgenic animal transgenic for an antibody or fragments thereof and having a phenotype reminiscent of a human pathology, that secrete the antibody.

Group 5, claim 23, drawn to a method of grafting into the brain of a non-human primate cells derivable from a non-human transgenic animal transgenic for an antibody or fragments thereof and having a phenotype reminiscent of a human pathology, that secrete the antibody.

Group 6, claims 24 and 25, drawn to methods of making a non-human animal transgenic for an antibody or fragments thereof and having a phenotype reminiscent of a human pathology.

Group 7, claims 26-28, drawn to methods of studying neurodegenerative disorders or pathologies of the muscular system using a non-human animal transgenic for an

antibody or fragments thereof and having a phenotype reminiscent of neurodegenerative syndromes, muscular atrophy/dystrophy, or immune disorders.

Group 8, claims 29-31, drawn to methods of using a non-human animal transgenic for an antibody or fragments thereof and having a phenotype reminiscent of neurodegenerative syndromes, muscular atrophy/dystrophy, or immune disorders to select compounds pharmacologically effective for treatment of neurodegenerative syndromes, muscular atrophy/dystrophy, or immune disorders.

Group 9, claims 32 and 33, drawn to a method of using a non-human animal transgenic for an anti NGF antibody or fragments thereof and having a phenotype reminiscent of a human pathology to screen compounds that potentiate the activity of nerve growth factor (NGF).

Group 10, claim 34, drawn to a method of using a non-human animal transgenic for an anti NGF antibody or fragments thereof and having a phenotype reminiscent of a human pathology to screen formulations of NGF that cross the blood brain barrier.

Group 11, claims 35, drawn to a method of preparing compositions that bind autoanti-NGF antibodies in the brain of Alzheimer's Disease subjects by using NGF.

Group 12, claim 36, drawn to a method of preparing compositions for treatment of muscular pathologies by using NGF.

Group 13, claim 37, drawn to a pharmaceutical composition comprising NGF.

The inventions listed as Groups 1-13 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1 is anticipated by Catteneo et al (Society for Neuroscience Abstract 301.18, 1996) who disclose a transgenic mouse expressing anti-NGF antibodies that has a phenotype reminiscent of neurodegeneration in that they display a 30% reduction of neurons in superior cervical ganglia. As a result there is no special technical feature linking the groups containing claims that depend from claim 1, i.e. groups 1 and 3-10. Further, 37 USC 1.475(b) does not allow for groupings of statutory classes of invention (i.e. compositions grouped with methods making and or use) when the inventions are not linked by a special technical feature. The technical feature linking groups 1 and 2 is "a human pathology." This is not a special technical feature as human pathologies were well known in the art at the time of the invention. The technical feature linking groups 1 and 11 is an antibody. This is not a special technical feature as antibodies were well known in the art at the time of the invention. There is no technical feature linking groups 1 and 13. The special technical feature of each group is considered to be as listed above in the restriction.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Richard Schnizer, Ph.D.